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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,149	02/26/2004	Iris Pecker	27595	2723

7590 08/10/2004

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EXAMINER	
DIBRINO, MARIANNE NMN	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/786,149	PECKER ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 26 February 2004 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claim 1 is pending and is currently being examined.

2. STIC Systems Branch of USPTO has corrected Applicant's CRF filed 2/26/04 as follows: Deleted invalid beginning/end-of-file text.

3. Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

> The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the Examiner on form PTO-892, they have not been considered.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 USPQ2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed method of detecting expression of a human heparanase gene which comprises a polynucleotide as set forth in SEQ ID NO: 1 in a human individual suspected of suffering from a blood cancer, the method comprising monitoring a protein expression or activity of said human heparanase gene in white blood cells of said individual in vitro, wherein the presence of said protein expression or activity indicates the expression of said human heparanase gene.

The instant claims a method of monitoring protein expression or activity of the product of a gene which comprises a polynucleotide as set forth in SEQ ID NO: 1. There is insufficient disclosure in the specification on such a complex.

The instant specification discloses on page 50 at lines 1-14 that both polyclonal and monoclonal antibodies were used successfully for detection of heparanase in intact cells by immunohistochemistry, and Table 3 on page 49 discloses 8 hybridomas and the antibodies they produce that react with human heparanase. The instant specification discloses at the paragraph spanning pages 11 and 12 that a biological sample is reacted with a heparanase specific molecular probe, i.e., an antibody (page 7 at lines 9-14), and detecting the localization and distribution of the said probe in situ. The instant specification discloses that potential existence of other human heparanases distinct from the human heparanase encoded by SEQ ID NO: 1, but that one other human heparanase is expressed in human placenta (especially pages 9-10). In addition, the specification further discloses that measurements of heparanase activity, i.e., expression and secretion, is measured by conversion of high MW HSPG substrate (pages 5, 6 and the paragraph spanning pages 31 and 32).

The instant claim language is not limited to detection of protein via monitoring with an antibody specific for the protein product of SEQ ID NO: 1, nor does it correlate activity of heparanase with the said protein product of the recited polynucleotide sequence. There is insufficient description of monitoring protein expression of a human heparanase gene which comprises a polynucleotide as set forth in SEQ ID NO: 1 where the monitoring is not by use of an antibody specific for the said protein product, and there is insufficient description of monitoring heparanase protein activity that correlates with the expression product of a human heparanase gene which comprises the recited

polynucleotide wherein the white blood cells are not assessed for correlation with expression of the protein product comprising SEQ ID NO: 1.

7. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not disclose how to practice the method of detecting expression of a human heparanase gene which comprises a polynucleotide as set forth in SEQ ID NO: 1 in a human individual suspected of suffering from a blood cancer, the method comprising monitoring a protein expression or activity of said human heparanase gene in white blood cells of said individual in vitro, wherein the presence of said protein expression or activity indicates the expression of said human heparanase gene. The specification has not enabled the breadth of the claimed invention in view of the teachings of the specification because the claim encompasses detection of protein via monitoring with something other than an antibody specific for the protein product of SEQ ID NO: 1, and it encompasses detection of heparanase activity, the said activity of heparanase does not necessarily correlate with the said protein product of the recited polynucleotide sequence.

The instant specification discloses on page 50 at lines 1-14 that both polyclonal and monoclonal antibodies were used successfully for detection of heparanase in intact cells by immunohistochemistry (and pages 36-37), and Table 3 on page 49 discloses 8 hybridomas and the antibodies they produce that react with human heparanase. The instant specification discloses at the paragraph spanning pages 11 and 12 that a biological sample is reacted with a heparanase specific molecular probe, i.e., an antibody (page 7 at lines 9-14), and detecting the localization and distribution of the said probe in situ. The instant specification discloses that potential existence of other human heparanases distinct from the human heparanase encoded by SEQ ID NO: 1, but that one other human heparanase is expressed in human placenta (especially pages 9-10). In addition, the specification further discloses that measurements of heparanase activity, i.e., expression and secretion, is measured by conversion of high MW HSPG substrate (pages 5, 6 and the paragraph spanning pages 31 and 32).

There is insufficient guidance in the specification as how to practice monitoring protein expression of a human heparanase gene which comprises a polynucleotide as set forth in SEQ ID NO: 1 where the monitoring is not by use of an antibody specific for the said protein product, or monitoring heparanase protein activity that correlates with the expression product of a human heparanase gene which comprises the recited polynucleotide wherein the white blood cells are not assessed for correlation with expression of the protein product comprising SEQ ID NO: 1. There is insufficient guidance in the specification as to how to practice the method of the instant invention. Undue experimentation would be required of one skilled in the art to practice the instant invention. See In re Wands 8 USPQ2d 1400 (CAFC 1988).

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: monitoring is by use of an antibody specific for the said protein product, or monitoring heparanase protein activity that correlates with the expression product of a human heparanase gene which comprises the recited polynucleotide wherein the white blood cells are assessed for correlation with expression of the protein product comprising SEQ ID NO: 1.

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,531,129 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the protein of the method of '129, SEQ ID NO: 2, is encoded by the polynucleotide of claim 1 of the instant application, SEQ ID NO: 1, and '129 discloses detecting heparanase protein in white blood cells of human individuals suspected of suffering from a blood cancer (especially column 11 at lines 19-48, columns 14-16, columns 23-24 and column 28).

13. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 14 of U.S. Patent No. 6,699,672 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the protein of the method of '672, SEQ ID NO: 2, is encoded by the polynucleotide of claim 1 of the instant application, SEQ ID NO: 1, and '672 discloses detecting heparanase protein in white blood cells of human individuals suspected of suffering from a blood cancer (especially column 11 at lines 12-40, columns 13-16, columns 22-24 and columns 27- 28).

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Chan Y Christina, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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